DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
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July 10, 2006

VIA FED-EX

In reply refer to Warning Letter SEA 06-37

Choraphor.com
14150 Northeast 20th Street, F1
PMB 368
Bellevue, Washington 98007

WARNING LETTER

Dear President/Owner:

This letter concerns your firm's marketing of the product "Choraphor" on your website, www.choraphor.com. According to information on your website, "Choraphor is a sulfate based solution that contains trace metals within an aqueous herbal base, as well as ammoniated acid in deionised water." This product is intended to prevent, treat, or cure disease conditions, or to affect the structure or function of the body. Statements on your website that document these intended uses include, but are not limited to, the following:

Choraphor

- *"Choraphor has been proven to eliminate the herpes virus on direct contact."*
- *"Some users have reported that symptoms are eliminated after treatment with no returning outbreaks, even after several years!"*
- *"Choraphor speeds up the healing and recovery time of outbreaks, dramatically."*
- *"Healing process begins almost Immediately!"*
- *"Effective against HSV1 and HSV2, Cold Sores, Genital Herpes and Fever Blisters."*
- *"It is, quite simply, the best medicine I have ever used for cold sores."*
- *"Choraphor is a topically applied skin solution that is effective against the herpes virus."*
- *"Choraphor offers you confidence in controlling your outbreaks and in some cases users have reported that they have not had any further outbreaks after using Choraphor."*

- *"Choraphor does not suppress the herpes virus, it destroys it."*
- *"Choraphor works by eliminating the virus on direct contact with the outbreak. It is an antiviral topical solution that helps to rapidly heal herpes lesions, blisters and sores rapidly, and then reduces any further recurrences."*
- *"Outbreaks diminish in frequency and intensity."*
- *"Choraphor is by far the best herpes treatment that I have come across to date."*
- *"Clinical studies have found that the herbal extract in Choraphor is effective in reducing the frequency and severity of recurrent episodes of herpes labalis (oral cold sores) and herpes genitalis (genital herpes)."*
- *"It has cured my HSV1 COMPLETELY!"*
- *"Eliminates the herpes virus on direct contact with the sore, lesion, or blister."*
- *"Choraphor can be applied safely and effectively on all types of the Herpes simplex virus (HSV-1 and 2).*
  This includes:
  1. *Oral Herpes and Cold Sores (affecting the mouth and lips)*
  2. *Genital Herpes (in both males and females)*
  3. *Facial Herpes (such as on the nose, nostrils, cheeks and forehead)*
  4. *Herpes Whitelow (affecting the fingers and hands)*
  5. *Other infected skin areas (such as arms, legs, scalp, buttocks and tail-bone)"*
- *"I have not taken my suppressive medication since I started to use Choraphor."*
- *"I have been on Valtrex regularly for several months and I believe it made my occurrences more frequent rather then preventative. I got your product and discontinued use of Valtrex altogether."*

These claims are further supplemented by the metatags that you use to bring consumers to your website. The metatags include "herpes cure," "herpes treatment," "genital herpes cure," "genital herpes treatment," and "herpes simplex."

Choraphor is a drug, as defined by section 201(g)(1) of the Federal Food, Drug and Cosmetic Act (Act), 21 U.S.C. § 321(g)(1), because it is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. Moreover, this product is a new drug, as defined by section 201(p) of the Act, 21 U.S.C. § 321(p), because it is not generally recognized as safe and effective for its labeled uses. Under sections 301(d) and 505(a) of the Act, 21 U.S.C. §§ 331(d) and 355(a), a new drug may not be introduced or delivered for introduction into interstate commerce unless an FDA-approved application is in effect for it. Your sale of Choraphor without such an approved application violates these provisions of the Act.

Furthermore, because this product is offered for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners, adequate directions cannot be written so that a layman can use this product safely for its intended uses. See 21 CFR § 201.5. Thus, Choraphor's labeling fails to bear adequate directions for its intended uses, causing it to be misbranded under Section 502(f)(1) of the Act, 21 U.S.C. § 352(f)(1).

The above violations are not intended to be an all-inclusive list of deficiencies. It is your responsibility to ensure that the drug products that you manufacture or distribute meet all of the requirements of the Act and its implementing regulations. Federal agencies are advised of the issuance of all warning letters about drugs and devices so that they may take this information into account when considering the award of contracts.

You must immediately correct these violations. If you do not immediately correct them, you may be subject to enforcement action without further notice. The Act provides for the seizure of illegal products and for an injunction against the manufacturer and distributors of illegal products. Individuals and businesses that violate the Act may also be subject to criminal prosecution.

You must notify this office in writing within 15 working days of receipt of this letter as to the steps that you have taken to correct the above-listed violations and to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be made. Additionally, if your firm does not manufacture the product identified above, your reply should include the name and address of the manufacturer. If the firm from which you receive the product is not the manufacturer, include the name of your supplier in addition to the manufacturer. Address your reply to the U.S. Food and Drug Administration, 22201 23rd Drive Southeast, Bothell, Washington 98021-4421, Attention: Lisa Althar, Compliance Officer.

A description of the new drug approval process can be found on FDA's internet website at http://www.fda.gov/cder/regulatory/applications/default.htm. Any questions you may have regarding this process should be directed to the Food and Drug Administration, Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, 5600 Fishers Lane, Rockville, Maryland 20857.

Sincerely,

Charles M. Breen
District Director

cc: John Spurge
Choraphor Pty Ltd.
19 Byrnes Street
Mareeba, Queensland 4880
Australia